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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,866	03/22/2001	Maria Emanuel Ryan	178-261 PCT/	8018

23869 7590 01/29/2003

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EXAMINER
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DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/787,866

Applicant(s)

RYAN ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 5-9, 15-17, 22-26 and 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-14, 18-21 and 28-31 is/are rejected.
- 7) ☒ Claim(s) 10 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The following is responsive to Applicant's election/amendment received Nov. 13, 2002.

Applicant's election of doxycycline without traverse is acknowledged. No prior art with respect to the use of "doxycycline" to treat cataracts was found. Therefore the search was expanded to the non-elected species, 4-dedimethylamino-tetracycline.

### ***Priority***

1. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by

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(1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

#### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement received June 25, 2001 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Specification***

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Objections***

3. Claims 15,16,17, 32-34 are objected to because of the following informalities: said claims refer to structures which are not in the claims themselves but are provided separately at the end of the application. It is respectfully requested that Applicant incorporate the structures into drawings (figures) and the claims should be amended to refer to the figures in which the structures may be found. Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

4. Claims 15, 16, 32, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "lower alkyl" in claims 15, 16, 32, 33 is a relative term which renders the claim indefinite. The term "lower alkyl" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has not conveyed to one of ordinary skill in the art the number of carbon atoms which fall within the term "lower alkyl". As a result, the metes and bounds of the patent protection desired is unclear.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-4, 11-14, 18-21, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al, 5,929,055. w/d

Ryan et al. disclose a therapeutic method for the management of diabetes. Specifically, Ryan et al. disclose a method of reducing the development or progression of a diabetes-associated pathological complication in a mammal. The method comprises administering effective amounts, i.e. an amount that has substantially no antimicrobial activity, of a tetracycline derivative such as 4-dedimethylamino-tetracycline. Examples of pathological complications are various nephropathies, various retinopathies and cataract of the lens of the eye. Ryan et al. disclose that

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the tetracycline derivatives serve to ameliorate or reduce/eliminate the pathological complications. Finally, the tetracycline derivatives may be administered orally, topically, by injection or the derivatives may be administered by time-release or controlled delivery formulations. Please see col. 5, lines 39-47; col. 6, lines 28-33; col. 7, lines 40-44; col. 9, lines 20-54; col. 13, lines 18-20; col. 14, lines 39-44.

Ryan et al. does not specifically disclose that the method reduces the risk of cataract development nor does Ryan et al. specifically disclose a cataract treatment method; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to select any of the pathological conditions, specifically cataracts, taught by Ryan et al. because one of ordinary skill in the art would have the reasonable expectation that any of the pathological conditions, especially cataracts, would be treated by the disclosed method. Moreover, Ryan et al. raise reasonable expectation of success by suggesting the cataracts would be treated by the disclosed tetracycline derivatives.

With respect to reducing the risk of cataract development, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the tetracycline derivatives prophylactically because one of ordinary skill in the art, based on the desirable teachings of Ryan et al. would reasonably expect the tetracycline derivatives to not only treat cataracts in diabetic patients but also reduce the risk of their development. This is further evidenced by Ryan et al. at col. 7, line 42-43, where it is disclosed that the pathological condition would be "reduced."

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9. Claims 10, 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. wld

***Conclusion***

Claims 1-4, 11-14, 18-21, 28-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Jan. 27, 2003



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600